



Our STN: BL [#####/0]

[COMPANY NAME]
Attention: [AUTHORIZED OFFICIAL'S NAME]
[AUTHORIZED OFFICIAL'S TITLE]
[ADDRESS]

Dear [AUTHORIZED OFFICIAL'S NAME]:

We have received your biologics license application submitted under Section 351 of the Public Health Service Act.

We completed an initial review of your application dated [DATE OF COVER LETTER] for [PROPER NAME] to determine its acceptability for filing. On [DATE OF LETTER] we notified you that your application was deficient and refused to file your application. You requested a meeting on [DATE OF -REQUEST] between your representatives and FDA staff concerning our refusal to file your application. Subsequent to that meeting, you requested on [DATE OF REQUEST] that the application be filed.

In response to your request, your application is considered to be filed the date we received your request to file the application. The review goal date is [6-MONTH OR 10-MONTH GOAL DATE, AS APPLICABLE].

USE IF THE APPLICATION IS ON THE APPLICATION INTEGRITY POLICY (AIP) LIST AND IF WE HAVE NOT YET DETERMINED THAT THE DRUG IS MEDICALLY NECESSARY: We have determined that this application is subject to the provisions of the Application Integrity Policy (AIP). We will not begin review until you are notified by the Director, Center for Biologics Evaluation and Research, that we have revoked the AIP, unless we determine that the AIP no longer applies to this application or that the product is medically necessary. [You may access the AIP list at http://www.fda.gov/ora/compliance_ref/aiplist.html](http://www.fda.gov/ora/compliance_ref/aiplist.html)

This acknowledgment of filing does not mean that a license has been issued nor does it represent any evaluation of the adequacy of the data submitted. Following a review of the application, we shall advise you in writing as to what action has been taken and request additional information if needed.

INSERT PARAGRAPH FOR BLOOD AND PLASMA: NOTIFICATION TO APPLICANTS THEY MAY MANUFACTURE AND STORE SOURCE PLASMA LABELED WITH THEIR U.S. LICENSE NUMBER, BUT MAY NOT SHIP UNTIL WE APPROVE THEIR BLA:
If you are applying for a U.S. license to manufacture Source Plasma, you may begin manufacturing. You may not ship any Source Plasma until we have approved your BLA.

INSERT OPTIONAL PARAGRAPH WHEN CBER RECEIVES ESTABLISHMENT
INFORMATION THAT IS NOT REQUIRED (specified product) AND MAY NOT REVIEW
THE APPLICATION:

Your submission included establishment information that is not required as part of a biologics license application for this type of product. Please refer to the CMC guidance document, “Guidance for Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product of a Monoclonal Antibody Product for In-Vivo Use” for the information you should include in your application to CBER. We will assess this information during the pre-license inspection of your establishment, but not as part of your application. Its inclusion in the file does not constitute approval.

Should you need additional information or have any questions concerning administrative or procedural matters please contact the Regulatory Project Manager, [NAME], at (301) [NUMBER].

Sincerely yours,

Appropriate signature block

